



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0754; FRL-9365-5]

Agency Information Collection Activities; Proposed Renewal of an Approved Collection; Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit a request to renew an existing approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: “Pesticide Data Call-In Program” and identified by EPA ICR No. 2288.02 and OMB Control No. 2070-0174, is currently scheduled to expire on November 30, 2012. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the ICR.

DATES: Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2011-0754, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Cameo Smoot, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5454; fax number: (703) 308-5884; email address: smoot.cameo@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What Information is EPA Particularly Interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or

other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What Should I Consider when I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the collection activity.
7. Make sure to submit your comments by the deadline identified under **DATES**.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

III. What Information Collection Activity or ICR Does this Action Apply to?

Affected Entities: Entities potentially affected by this ICR include pesticide registrants, which may be identified by the North American Industrial Classification System (NAICS) code 32532, pesticide and other agricultural chemical manufacturing.

Title: Pesticide Data Call-In Program.

ICR number: EPA ICR No. 2288.01.

OMB control number: OMB Control No. 2070-0174.

ICR status: This ICR is currently scheduled to expire on November 30, 2012.

EPA will be seeking a short renewal of the currently approved ICR. This short renewal will provide additional time to allow EPA to finish working to restructure the ICR, improve the electronic forms and instructions, and consult with stakeholders and OMB on those ICR changes and the corresponding adjustments to the burden estimates. This extension is necessary because the ICR covers ongoing activities that are required to support the statutorily mandated pesticide reviews.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), every pesticide product must be registered with EPA. An applicant for registration must supply data to demonstrate that the pesticide product will not cause “unreasonable adverse effects” on humans or to the environment. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA must determine, from data supplied by the applicant or

registrant, that the level of pesticide residues in food and feed will be safe for human consumption, defined as “a reasonable certainty that no harm” will result from exposures to pesticide residues. Although data is provided with the initial applications, the Agency issues Data Call-Ins (DCIs) when it has determined that more information is necessary to make the necessary decision pursuant to the mandates in FIFRA and FFDCA.

The programs represented in this proposed ICR renewal and consolidation share a common statutory authority, section 3(c)(2)(B) of FIFRA, which authorizes EPA to require pesticide registrants to generate and submit data to the Agency, when such data are needed to maintain an existing registration of a pesticide. EPA’s determination that additional data are needed can occur for various reasons, with the following four reasons being the most common:

1. *Reregistration program.* Section 4 of FIFRA requires EPA to re-assess the health and safety data for all pesticide active ingredients registered before November 1, 1984, to “reregister” them, i.e., determine whether these “older” pesticides meet the criteria for registration that would be expected of a pesticide being registered today for the first time. FIFRA section 4 directs EPA to use FIFRA section 3(c)(2)(B) authority to obtain the required data. Although the Reregistration Eligibility Decisions are complete, the Agency may still need to issue DCIs to close out the program.

2. *Registration review program.* Section 3(g) of FIFRA contains provisions to help achieve the goal of reviewing each pesticide every 15 years to assure that the pesticide continues to pose no risk of unreasonable adverse effects on human health or the environment. FIFRA section 3(g) instructs EPA to use the FIFRA section 3(c)(2)(B) authority to obtain the required data.

3. *Special review program.* Though rare, EPA may conduct a special review if EPA believes that a pesticide poses risks of unreasonable adverse effects on human health or the environment. Section 3(c)(2)(B) of FIFRA provides a means of obtaining any needed data.

4. *Anticipated residue/percent crop treated information.* Under section 408 of FFDCA, before a pesticide may be used on food or feed crops, the Agency must establish a tolerance for the pesticide residues on that crop or establish an exemption from the requirement to have a tolerance. Section 408(b)(2)(E) and (F) of FFDCA authorize the use of anticipated or actual residue (ARs) data and percent crop treated (PCT) data to establish, modify, maintain, or revoke a tolerance for a pesticide. The FFDCA requires that if AR data are used, data must be reviewed five years after a tolerance is initially established. If PCT data are used, the FFDCA affords EPA the discretion to obtain additional data if any or all of several conditions are met.

The Agency issues DCIs when it has determined that more information is necessary to make decision about pesticides pursuant to the mandates in FIFRA and FFDCA. Agency decisions requiring additional data are based on the data requirements set forth in 40 CFR parts 150 through 180, with the majority of the data requirements captured in 40 CFR parts 158 and 161.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range from 59 to 13,636 hours per response, depending on the review program and type of DCI issued. Burden is defined in 5 CFR 1320.3(b). The ICR provides a detailed explanation of this estimate, which is only briefly summarized here:

Frequency of collection: On occasion.

Estimated number of potential respondents: 1,643.

Estimated number of total annual responses: 184.

Estimated total annual burden on respondents: 262,301 hours.

Estimated total annual costs: \$12,506,726.

Changes in the estimates: The total estimated burden for this ICR is unchanged from that currently approved by OMB.

IV. What is the Next Step in the Process for this ICR?

EPA intends to submit the ICR to OMB for review and a short term approval (i.e., 12 months) pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects

Environmental protection, Reporting and recordkeeping requirements.

Dated: October 4, 2012.

James Jones,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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